MAR 2 - 2005

VII - 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS:

Submitted by:

Tadeusz Wellisz, M.D.
Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
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Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	November 8, 2004
Common/Usual Name:	Porous High Density Polyethylene (HDPE) Surgical Implants
Proprietary Names:	AOC™ Porous Polyethylene, AOC™ Porous HDPE, AOC™ Porous Polyethylene Surgical Implant, Cerepor™
Classification Name:	Polymer ENT Synthetic, Porous Polyethylene (per 21 CFR section 874.3620)

Predicate Devices

1. ePor, Inc.
   Porous HDPE Surgical Implants
   K022665

2. Ceremed, Inc.
   AOC™ Bone Wax
   K041363

3. Porex Surgical Inc.
   MEDPOR® Surgical Implant Material: Preformed Cranial and Facial Implants
   K922489

4. Porex Surgical Inc.
   MEDPOR® Plus Surgical Implant Biomaterial
   K012350

5. Porex Surgical Inc.
   MEDPOR® Craniofacial Implants with embedded Titanium Mesh
   K040364

Description of the device:

AOC™ Porous Polyethylene Surgical Implants are provided as blocks, sheets, and anatomical shapes, and are manufactured of porous high-density polyethylene (HDPE), a material that has been used in craniofacial reconstruction for over 25 years. The implants are provided with a coating of a water-soluble alkylene oxide copolymer blend. AOC Porous Polyethylene Implants are provided sterile by irradiation and must not be resterilized.

Intended use:

AOC™ Porous Polyethylene Surgical Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.

Substantial equivalence:

AOC™ Porous Polyethylene Surgical Implants have the same intended use and indications for use as the predicate devices made of porous polyethylene. The biocompatibility of the alkylene oxide copolymer blend is in accordance with the standards set forth in ISO-10993 Biological Testing of Medical and Dental Materials and Devices.

The mechanical properties of AOC™ Porous Polyethylene Surgical Implants are substantially equivalent to the corresponding properties of the predicate devices made of porous polyethylene, and any minor differences raise no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 - 2005

Tadeusz Wellisz, M.D.
President
Ceremed, Inc.
3643 Lenawee Avenue
Los Angeles, California 90016

Re: K043133
Trade/Device Name: AOC Porous Polyethylene
Regulation Number: 21 CFR 878.3500
Regulation Name: PTFE with carbon fibers implant
Regulatory Class: II
Product Code: KKY
Dated: January 14, 2005
Received: January 21, 2005

Dear Dr. Wellisz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XII. INDICATIONS FOR USE:

510 (k) Number (if known): K043133

Device Name: AOC Porous Polyethylene

Indications For Use:
AOC™ Porous Polyethylene Surgical Implants are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043133

Division Sign-Off

510(k) Number_____